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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,783	05/28/2002	Lynn Repsis Fraser	78104.037	6101

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EXAMINER	
AFREMOVA, VERA	
ART UNIT	**PAPER NUMBER**
1651	10

DATE MAILED: 09/17/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,783	FRASER, LYNN REPSIS	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1 and 34-57* is/are pending in the application.

4a) Of the above claim(s) *58-87* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1 and 34-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of the Group I (claims 1 and 34-57) in Paper No. 9 filed 6/24/2003 is acknowledged. The traversal is on the ground(s) that all claims have a special corresponding technical feature such as a composition with at least two agents. However, this is not found persuasive because the "special technical feature" (the technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art) is known in the prior art as explained in the prior office action. Thus, the unity of inventions is broken. The requirement is still deemed proper and is therefore made FINAL.

Claims 58-87 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in Paper No. 9 filed 6/24/2003.

Claims 1 and 34-57 are under examination in the instant office action.

Claim Objections

Claim 47 is objected to because of the following informalities:

Claim 47 appears to contain some typing error in claim dependency and it is believed to depend on claim 43 but not on 41. The instant claim 47 excludes the second agent that is required by claim 41 because both fertilization promoting peptide and adenosine are one modulator of adenosine receptor activity as encompassed by the claimed invention (see claim 43). Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 34, 35, 41, 42, 43 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,698,549 [A].

Claims are directed to a medication composition comprising a combination of two agents that are 1) angiotensin II and 2) a modulator of adenosine receptor activity or adenosine.

US 5,698,549 [A] discloses a medication composition intended for administration wherein the composition comprises a combination of two agents that are 1) angiotensin II and 2) a modulator of adenosine receptor activity or adenosine, for example: see col. 17, lines 16-17. The disclosed composition is identical to the presently claimed composition because it comprises identical components as required by the presently claimed invention. Thus, the effects that would be produced by the composition of the cited patent under the same conditions as intended for the instant invention are presumed to be inherently identical to the properties/effects as intended for the presently claimed composition. Thus, the cited patent is considered to anticipate the claimed invention.

Claims 1, 40, 41, 46 and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Schmid et al. [U].

Claims are directed to a medication composition comprising a combination of two agents that are 1) calcitonin and 2) angiotensin II. Some claims are further drawn to incorporation of a pharmaceutical carrier into the composition.

Schmid et al. disclose a pharmaceutical composition wherein the composition comprises a combination of two agents that are 1) calcitonin and 2) angiotensin II, for example: see the injection composition at figure 6. The disclosed composition is an injection and, thus, it comprises a suitable pharmaceutical carrier. The disclosed composition is identical to the presently claimed composition because it comprises identical components as required by the presently claimed invention. Thus, the effects that would be produced by the composition of the cited reference under the same conditions as intended for the instant invention are presumed to be inherently identical to the properties/effects as intended for the presently claimed composition. Thus, the cited reference is considered to anticipate the claimed invention.

Claims 1, 34, 35, 40, 41, 42, 43, 45, 52 and 53 are rejected under 35 U.S.C. 102(b) as being anticipated by US 6,153,582 [B].

Claims are directed to a medication composition comprising a combination of two agents that are 1) calcitonin and 2) a modulator of adenosine receptor activity or adenosine. Some claims are further drawn to incorporation of a suitable pharmaceutical carrier into the composition.

US 6,153,582 [B] discloses an animal cell medium composition (col. 3-4) wherein the composition comprises a combination of two agents that are 1) hormonal supplement or calcitonin (col. 4, line 35) and 2) adenosine (col. 4, line 14). The disclosed composition is

intended for culturing and/or maintaining animal cells and, thus, it comprises suitable pharmaceutical carriers including carriers for topical applications related to animal cells either corneal cells or sperm cells within the meaning of the instant claims. The disclosed composition is identical to the presently claimed composition because it comprises identical components as required by the presently claimed invention. Thus, the effects that would be produced by the composition of the cited patent under the same conditions as intended for the instant invention are presumed to be inherently identical to the properties/effects as intended for the presently claimed composition. Thus, the cited patent is considered to anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1 and 34-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 95/32725 [IDS-1], Suzuki et al. [IDS-2] and Fraser [IDS-4].

Claims are directed to a medication composition for increasing capacitation of mammalian sperm or treating infertility in humans wherein the composition comprises a combination of two agents or more agents selected from calcitonin, angiotensin II and a modulator of adenosine receptor activity. Some claims are further drawn to the use of a modulator of adenosine receptor activity selected from fertilization promoting peptide (FPP), adenosine or combination of FPP and adenosine in the composition. Some claims are further

drawn to incorporation of a suitable pharmaceutical carrier into the composition. Some claims are further drawn to the use of calcitonin derived from salmon, porcine or human sources. Some claims are further drawn to the use of particular concentrations of agents in the composition.

WO 95/32725 [IDS-1] discloses a medication composition for increasing capacitation of mammalian sperm or treating infertility in humans wherein the composition comprises agent such as angiotensin II (abstract). It also teaches the agent concentrations and suitable carriers for the medication composition for increasing capacitation of mammalian sperm or treating infertility in humans (examples 1-5). But it lacks disclosure related to the use of calcitonin, FPP and/or adenosine in the composition.

However, the reference by Fraser [IDS-4] discloses a medication composition for increasing capacitation of mammalian sperm or treating infertility in humans wherein the composition comprises agents such as fertilization promoting peptide (FPP) or adenosine or combination of FPP and adenosine in the composition (abstract). The reference also teaches the agent concentrations (page 242, col. 2). But it lacks the disclosure related to angiotensin II and calcitonin.

The reference by Suzuki et al. [IDS-2] teaches calcitonin as agent effective for increasing capacitation of mammalian sperm and, thus, for treating infertility in mammalians.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to combine three agents that are 1) angiotensin II, 2) calcitonin and 3) FPP and/or adenosine in one composition with a reasonable expectation of success for increasing capacitation of mammalian sperm or treating infertility in humans because each agent has been known and/or used in compositions for increasing capacitation of mammalian sperm or

treating infertility in mammalians including humans as adequately demonstrated by the cited prior art references. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinter, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960). Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary. It is considered to be within the purview of the ordinary skill practitioner to adjust agent concentrations with regard to a particular application and/or with regard to a various source of calcitonin agent including salmon, porcine and/or human sources of derivatization. It is considered to be within the purview of the ordinary skill practitioner to select the pharmaceutical carriers suitable for applications intended for increasing capacitation of mammalian sperm and treating infertility in mammalians including humans. One of skill in the art would have been motivated to adjust amounts and carriers for the expected benefits in maximizing effects related to sperm capacitation and mammalian infertility treatments.

Thus, the claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (703) 308-9351. The examiner can normally be reached on 9.30 am - 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Vera Afremova
AU 1651
September 16, 2003.

VERA AFREMOVA
PATENT EXAMINER